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HUMAN RANDOMIZED CONTROL TRIAL

Clinical evaluation of a novel protocol for supportive periodontal care: A randomized controlled clinical trial

Alexandra Stähli | **Jvana Ferrari** | **Anna Sophia Schatzmann** | **Lucienne Dominique Weigel** | **Andrea Roccuzzo** | **Jean-Claude Imber** | **Ho-Yan Duong** | **Sigrun Eick** | **Niklaus P. Lang** | **Giovanni E. Salvi** | **Anton Sculean**

Department of Periodontology, University of Bern, Bern, Switzerland

Correspondence
Alexandra Stähli, Department of Periodontology, University of Bern, Freiburgstrasse 7, CH-3010 Bern, Switzerland.
Email: alexandra.staehli@unibe.ch

Jvana Ferrari and Anna Sophia Schatzmann share second author position.

Abstract

Background: The aim of this study was to compare the clinical efficacy and the patient perception of subgingival debridement with either guided biofilm management (GBM) or conventional scaling and root planing (SRP) during supportive periodontal care (SPC).

Methods: Forty-one patients in SPC were randomly assigned to either treatment with GBM or SRP every 6 months. The primary outcome was the percentage of bleeding on probing (BoP) at 1 year. Moreover, pocket probing depths (PPD), recession, and furcation involvements were also measured. Full-mouth and specific site analyzes were performed at baseline, 6 and 12 months of SPC. Patient comfort was evaluated using a visual analogue scale (VAS) at 12 months.

Results: At 1 year, mean BoP percentage decreased from 12.2% to 9.0% ($p = 0.191$) and from 14.7% to 7.9% ($p = 0.004$) for the GBM and SRP groups, respectively. Furcation involved multirooted teeth but no through-and-through lesions were significantly fewer in the GBM than in the SRP group after 12 months ($p = 0.015$). The remaining parameters showed slight improvement in both groups without any statistically significant differences between the two groups after 1 year. Pain evaluation as patient reported outcome measures (pain evaluation) was in favor ($p = 0.347$) of the SRP group, while overall satisfaction was similar for both groups. Treatment time was not statistically significantly different between the two groups ($p = 0.188$).

Conclusion: In well-maintained SPC patients, SRP protocols resulted in significant clinical improvements in terms of BoP; however, for the other clinical improvements, similar efficacy for both GBM and SRP was observed.

KEYWORDS
dental hygiene, periodontal disease, prevention, scaling, subgingival, scaling, supragingival

1 | INTRODUCTION

The cause-and-effect relationship between biofilm colonization on teeth and the development of periodontal disease has been well-established for over five decades.[1–4] The consistent and thorough removal of biofilm, therefore, remains the cornerstone for achieving periodontal health and sustaining it over the long term.[5–7]

Typically, the professional removal of biofilm complements daily home care through tooth brushing and the use of interdental devices. It is well-documented that, if daily oral hygiene measures are not optimal, the remaining biofilm can calcify,[8] resulting in a rough surface that further promotes biofilm colonization.[9,10] Consequently, regular professional removal of biofilm and its calcifications plays a pivotal role in maintaining oral health.

Generally, biofilm removal is performed using hand instruments, and later on, sonic and ultrasonic devices were introduced.[11] More recently, a novel system of "air-polishing" gained attention and was promoted by the dental profession for subgingival use.[12]

Air-polishing has undergone several advancements aimed at enhancing clinical applications and improving patient-related outcomes.[13] Initially, sodium bicarbonate was the primary abrasive powder used for prophylaxis. However, owing to its abrasive properties, gentler powders such as glycine were developed specifically for subgingival air polishing.[14–17] More recently, the sugar alcohol erythritol with a particle size of 14 μm has been successfully applied in clinical practice.[18] Trials evaluating the adjunctive use of erythritol air-polishing powder applied during subgingival instrumentation demonstrated promising results.[19–21]

Obviously, the principle of air-polishing during SPC was put to scrutiny in several clinical studies,[20,22] including not only cohort studies, but also randomized controlled clinical trials.[23–29] In addition, four systematic reviews covering various parts of the available literature on this topic were published.[30–33] However, there is a gap in the presentation of the most recent clinical studies, particularly in well-maintained patients undergoing SPC. This gap justifies the undertaking of another randomized controlled clinical trial, which aims to provide a more comprehensive evaluation of the evidence, including patient-reported outcome measures.

Recently, the concept of guided biofilm therapy (GBT) was introduced by a company* emphasizing air-polishing coupled with biofilm disclosure. However, the application of the term "therapy" might not be fitting, as biofilm itself does not undergo therapeutic interventions. Consequently, we have adopted the term guided biofilm management (GBM).

Hence, the objective of this current study was to assess the clinical effectiveness and patient-related outcome measures of air-polishing in comparison to the traditional mechanical removal of biofilm during supportive periodontal care (SPC).

2 | MATERIALS AND METHODS

2.1 | Study design and ethical approval

This study was designed as a randomized controlled clinical trial including two parallel groups (Figure 1). Ethical approval was obtained by the ethical board for human experimentation of the Canton of Bern, Switzerland (ID2019-00046). The study was registered at clinical.trials.gov NCT05799261 and conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. The manuscript was prepared according to the CONSORT checklist for improving the quality of reporting randomized controlled trials.

2.2 | Sample size calculation

The sample size calculation applied prior to the recruitment was based on the primary outcome of percentage of bleeding on probing (BoP).[34] The expected mean difference was 3% and the expected standard deviation was 2.5% per group. Eleven patients per group were required to detect 5% difference between groups assuming a standard deviation (SD) of 2.5%, a power of beta = 0.9 and alpha = 0.05. The necessary sample size was increased to 20 participants per group to account for drop-outs during the study duration.

2.3 | Inclusion criteria

A total of 59 patients from the patient pool of the Department of Periodontology, University of Bern, Switzerland, were consecutively enrolled starting from January 2022 until May 2022. All patients adhered to SPC on the basis of their clinical status and having been treated for periodontitis stage I, II, and III, and IV Grade A, B.[35] All patients had residual probing depths of less than 6 mm during SPC. Active periodontal treatment was completed at least 3 years before study enrollment.

* EMS, Nyon, Switzerland

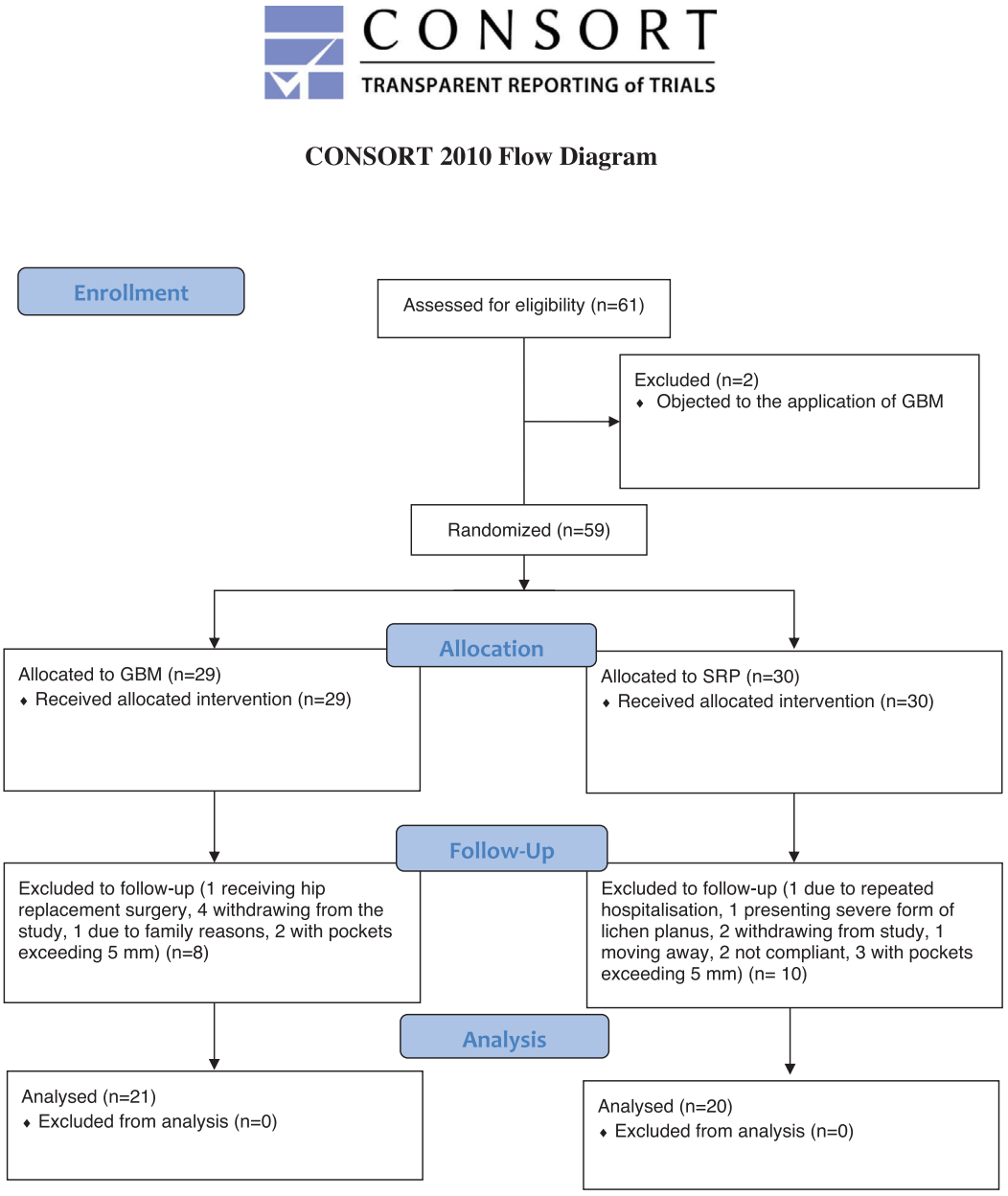

FIGURE 1 Consort flow chart

2.4 | Randomization

Block randomization was performed and patients were randomly allocated to GBM and SRP group. Randomization was conducted by a biostatistician not involved in the study who prepared sealed envelopes entailing the allocation. Randomization was balanced for smoking, sex, and BoP.

2.5 | Screening and informed consent

The examiners explained to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits, and any discomfort it may entail. Each participant was informed that the participation in the study was voluntary and that he or she may withdraw from the study at any time and that withdrawal of consent would not have affected subsequent medical assistance and treatment.

Using the approved form, written consent of a participant was obtained before any study procedures were performed. Participants did not receive any compensation or payment. None of the patients had significant concomitant diseases. Neither were they enrolled in any previous clinical trial. Screened were initially 61 patients.

2.6 | Study endpoints

Primary endpoint was the change of BoP.[34]

This is a quantitative variable, which is defined as the percentage of bleeding sites out of the total number of sites. Hereby, all gingival sulci and pockets were measured with a periodontal probe.[†] and bleeding sites as well as full mouth pocket probing depth (PPD) were recorded. Furcation involvement was further assessed and classified as ≤3 or >3 mm.

The secondary end-points were: Change in PPD, gingival recessions, furcation involvement, patient comfort (patient-reported outcome measures [PROMs]), and evaluation of time effectiveness. Using a VAS of 100 mm patients were asked to evaluate their perception of pain and satisfaction with the treatment. Treatment time was recorded in minutes.

2.7 | Study procedures

The overall study duration was planned to be 3.5 years comprising 6 months of participant enrolment and 3 years of effective study duration for each patient.

At the first visit, a sealed envelope with the allocation to a group was opened by the dental hygienist performing the SPC. Clinical measurements at the beginning of each visit were performed by a masked dentist of the Department of Periodontology (A.St., L.W., A.R., J.C.I.).

The test group was treated according to a novel treatment concept (GBM):

1. Staining of all tooth surfaces to detect any soft and hard deposits.[36]
2. Removal of supra- and subgingival soft bacterial deposits by means of an erythritol-based air-flow system.
3. If present, the supra- and subgingival hard deposits (e.g., calculus) were removed by means of a slim ultrasonic tip[‡] without any additional use of hand instruments (curette). Root surfaces are being checked with a DH2 probe.[§]
4. Control of root surface smoothness with a DH2 probe.
5. Another sub- and supragingival application of erythritol powder air-flowing without any rubber cup polishing. In this group, no hand instruments were used and no rubber cup polishing was performed.

The control group received conventional scaling and root planing (SRP) as part of SPC:

1. Removal of supra- and subgingival hard and soft deposits by means of hand instruments (curettes) and ultra-sonic scalers.
2. Control of root surface smoothness with a DH2 probe.
3. Polishing with rubber cup and paste

All patients were recalled for two visits per year with a planned study duration of 3 years. The present paper reports on the 1-year results.

2.8 | Statistical analyses

The null hypothesis stated that there was no statistically significant difference between the intervention groups regarding all outcomes. The alternative hypothesis stated that there was a statistically significant difference between the intervention arms regarding the outcomes. A two-sided test at the alpha = 0.05 was used for all statistical analyses. Descriptive statistics were calculated and tabulated at baseline per group as means (sds) or medians for continuous and as % for binary outcomes. Normality of the distribution was evaluated assessing skewness and kurtosis and applying the Kolmogorov-Smirnov test. All continuous variables were presented as means ± SD when normally distributed and as medians and interquartile ranges when not normally distributed. Categorical variables were reported as frequencies and percentages. Continuous variables were tested for differences with the Wilcoxon signed-rank test. Categorical variables were tested by the Pearson's $\chi 2$-test or the Fisher's exact test where appropriate. The differences between patients in the treatment groups were determined at each time point using the Mann-Whitney *U*-test. All statistical analyses were performed using a specialized software.[‖]

3 | RESULTS

3.1 | Risk of bias

For evaluating the risk of bias of the present study, the PRISMA checklist (Preferred Recording Items for Systematic Reviews of randomized controlled clinical trials) was used[37]. Out of the 13 domains, 11 could be answered positively. Only question 4 and 5 have to be denied. The participants could not be blinded to the treatment assignment owing to the difference of the two procedures tested.

[†] Hu-Friedy Group, PCP UNG 15, Chicago, IL, USA
[‡] Piezon/PS, EMS, Nyon Switzerland
[§] Deppeler SA, Rolle, Switzerland

[‖] SPSS 28.0 IBM, Chicago, IL, USA

TABLE 1 Patient characteristics

Characteristics	GBM group	SRP group
Sex	11 f /10 m	10 f/10 m
Smoking	1	2
Mean BoP baseline	12.2%	14.7%
Mean PPD baseline	2.42 mm	2.44 mm
Mean number of furcation involved teeth baseline	5.00	6.80

Abbreviations: BoP, bleeding on probing; GBM, guided biofilm management; PPD, pocket probing depth; SRP, scaling and root planing.

Likewise, those delivering treatment could not be blinded to treatment assignment for the same reason. However, the clinicians who assessed the outcome measures were blinded. No unintended side effects of harms of the study population was observed.

3.2 | Calibration of clinicians

Inter- and intra-operator calibration was performed three times (at study initiation, and every 3 months) on other patients not involved in the study. An initial mean kappa score of 0.79 was obtained. Disagreement was discussed and evaluated with all three clinicians so that a final kappa score of 0.94 was reached.

3.3 | Patient flow

Prior to recruitment, two patients were screened but denied participation because of a dislike of the new technology. Out of the 59 patients in SPC, 41 were analyzed after 1 year (for patient characteristics, see Table 1). Eighteen subjects dropped out because of various reasons: repeated hospitalization with a prolonged use of antibiotics (1), hip replacement surgery (1), onset of severe oral lichen planus (1), voluntary withdrawal (6), family reasons (1), moving-away (1), non-compliance (2), and sudden deterioration of single pockets exceeding PPD > 5 mm (five, equally distributed between groups [two for GBM, and three for SRP]).

3.4 | Primary outcome

At baseline, the mean BoP percentages for the two groups were 12.2% (SD, 9.2%) and 14.7% (SD, 8.9%) for the GBM and SRP group, respectively. The groups did not yield a statistically significant difference in BoP percentage at baseline.

After 1 year, the mean BoP percentages for the two groups were 9.0% (SD, 6.4%) and 7.9% (SD, 4.2%) for the GBM and SRP group, respectively (Figure 2A). The control (SRP) group demonstrated a statistically significant improvement ($p = 0.04$), while the reduction of BoP percentage of the test group did not reach statistical significance (Figure 2A).

3.5 | Secondary outcomes

At baseline, the mean PPD was 2.42 mm (SD, 0.28 mm) and 2.44 (SD, 0.29 mm) for the GBM and the SRP group, respectively. These values did not differ from each other (Figure 2B). After 1 year, the mean PPD was 2.39 mm (SD 0.32 mm) and 2.43 mm (SD, 0.31 mm) for the GBM and SRP group, respectively (Figure 2B). Neither the differences between baseline and 1 year nor between the groups were statistically significant.

Analyzing sites with a PPD of 4 and 5 mm with BoP positivity yielded no differences between baseline and 1 year for both groups. Neither were the values between test and control group significantly different (Figure 3).

At baseline, the number of sites displaying recession in the test (GBM) did not differ from that of the SRP group (Figure 4A). After 1 year, comparable numbers were registered for both groups. No statistically significant differences were found neither between the recession means between groups nor over time (Figure 4B).

At baseline, the number of furcation involved multirooted teeth (≤3 mm) was 4.95 (SD, 3.62) and 6.55 (SD, 4.52) for the GBM and SRP group, respectively. This difference did not reach statistical difference. After 1 year, the number of initial furcation involvements (≤ 3 mm) was 4.95 (SD, 3.62) and was slightly, but not statistically significantly ($p = 0.055$) reduced to 3.38 (SD, 3.93) in the GBM group. In the control (SRP) group, the number of initial furcation involvements did not change statistically significantly after 1 year 6.45 (SD 4.52). Furcation involved multirooted teeth both of ≤3 mm and > 3 mm but not through-and-through lesions showed no differences between the groups at baseline, but a significant difference after 12 months: 3.43 for GBM and 6.65 for SRP; $p = 0.015$ (Figure 4C).

3.6 | PROMs

The PROMs were assessed with a questionnaire to the patient using a VAS of 100 mm. Regarding pain perception the values were at 15 mm (SD, 13 mm) for the GBM and 7.6 mm (SD, 12 mm) for the SRP group, respectively ($p = 0.035$) (Figure 5).

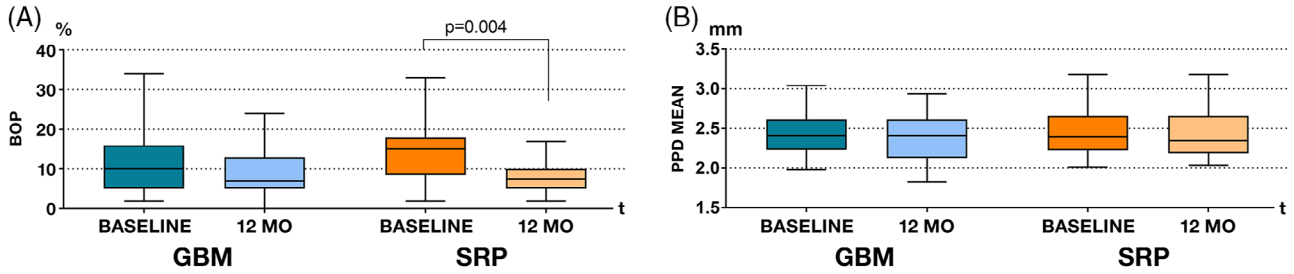

FIGURE 2 (A) Median BoP percentage for GBM and SRP at baseline and after 1 year. (B) Median PPD in mm for GBM and SRP at baseline and after 1 year. BoP, bleeding on probing; GBM, guided biofilm management; PPD, pocket probing depth; SRP, scaling and root planing

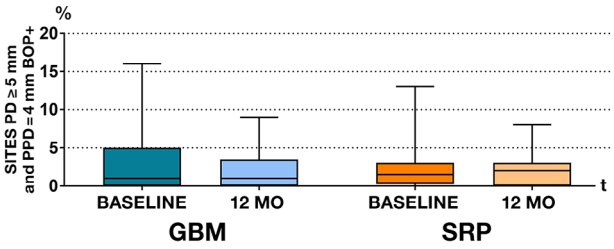

FIGURE 3 Median number of sites with PPD 4 and 5 mm and concomitant BoP positivity for GBM and SRP at baseline and after 1 year. BoP, bleeding on probing; GBM, guided biofilm management; PPD, pocket probing depth; SRP, scaling and root planing

Regarding the perception of the entire procedure, the GBM group was satisfied to 84.8 mm (SD, 22.5 mm) and the SRP group to 97.3 mm (SD, 5.2 mm). This difference did not reach statistical difference ($p = 0.068$).

3.7 | Time effectiveness

The average treatment duration starting for the GBM group at the timepoint of staining was 42.4 min (SD, 6.0 min). For the SRP group, time measurement started with the instrumentation and averaged 39.6 min (SD, 6.9 min). The intergroup difference was not statistically significantly different ($p = 0.118$).

4 | DISCUSSION

The present RCT has compared the clinical efficacy and PROMs of subgingival debridement with either GBM or conventional SRP during SPC. Both treatment modalities resulted in comparable clinical outcomes in the clinical and patient-reported outcomes.

The cohorts of patients of the present study were long-term documented patients of the Department of Periodontology at the University of Bern, Switzerland, who had been treated for active periodontal disease at least 3 years ago and had been kept in regular maintenance ever since. It should, therefore, be realized that these patients had successfully undergone SPC exhibiting a high standard of biofilm control on their own through daily practices (their initial PI being less than 20%). This is also reflected in the initial mean BoP percentage of 12.2% and 14.7%, respectively. While in the GBM group, the improvement in BoP did not reach statistical significance compared to baseline, a statistically significant improvement was observed in the SRP group. Nevertheless, the final BoP values after the SPC procedures reached equally low values of 9.0% and 7.9%, respectively. The fact, that the difference in the SRP group reached statistical difference is most likely due to the fact that the baseline value was slightly, but not statistically significantly higher than that of the GBM group.

When analyzing sites with probing depths of 4 and 5 mm that exhibited BoP, no statistically significant differences could be identified between the GBM and SRP groups, respectively. Additionally, there were no longitudinal improvements observed from the initial to the final examinations. It should be noted that, when comparing the test and control groups, there was no statistically significant difference in terms of the change in the primary outcome. Recent systematic reviews[30–33] presented similar outcomes for the primary outcome variable of the present study, namely BoP. In essence, all the short-term studies conducted between 2003 and 2022, which compared the air-flow system with SRP over a period of ≤6 months or 12 months, failed to demonstrate any statistically significant differences in terms of changes in BoP between the two treatment modalities.[13,14,21,23,25,26,38–43]

When examining the secondary outcomes, there were no statistically significant differences between the GBM and SRP procedures during SPC with respect to PPD. Neither between the two groups nor longitudinally were there any noteworthy changes. The absence of statistically significant change could be attributed to the fact that all patients initially presented with few substantial residual pockets, and where present, these pockets never exceeded depths of ≥5 mm.

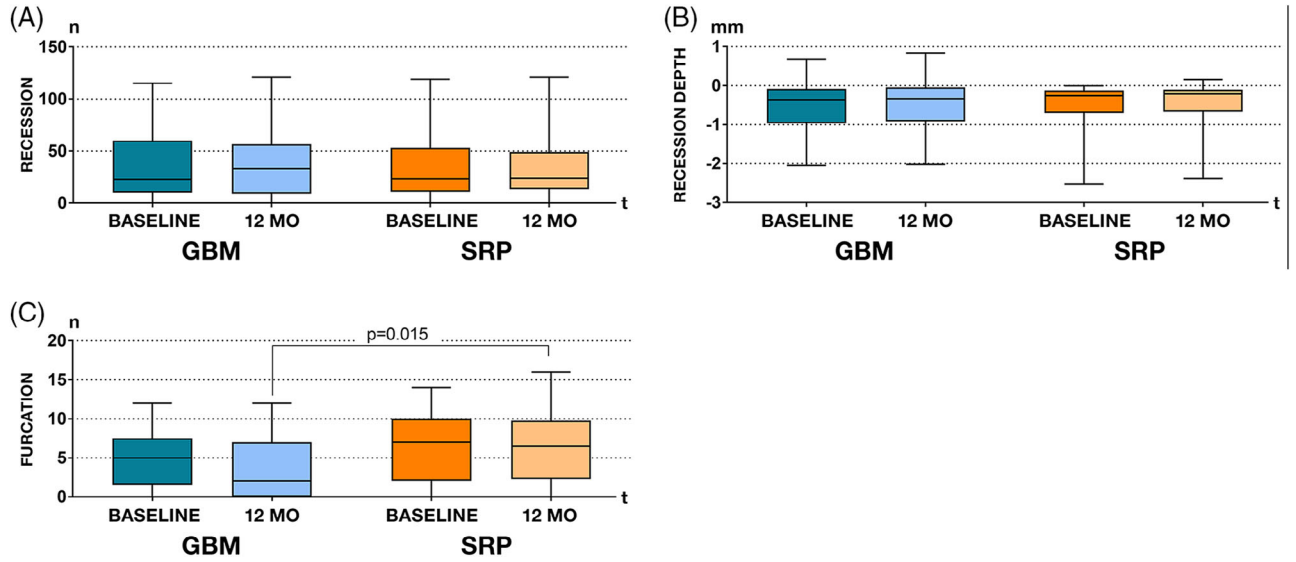

FIGURE 4 (A) Median number of recession for GBM and SRP at baseline and after 1 year. (B) Median recession depths in mm. (C) Median number of furcation involvements (Class I) for GBM and SRP at baseline and after 1 year. GBM, guided biofilm management; SRP, scaling and root planing

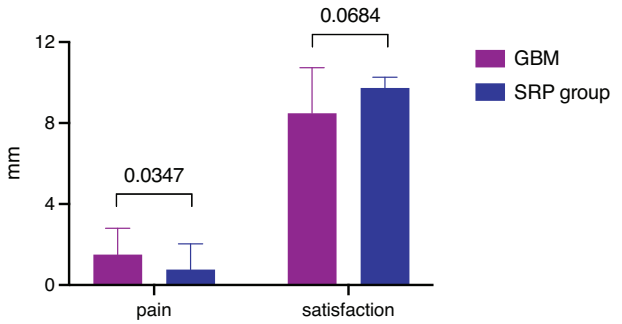

FIGURE 5 Mean and SD of pain and overall satisfaction VAS for GBM and SRP after the SPC procedures. GBM, guided biofilm management; SD, standard deviation; SPC, supportive periodontal care; SRP, scaling and root planing; VAS, visual analogue scale

Likewise, there were no statistically significant differences in the mean changes in PPD across the 11 studies presented in the aforementioned systematic reviews.[30–33] Pocket depth changes were almost identical for air-flow and SRP. Nevertheless, there is a very similar study like the present one performed by the same group at the University of Bern indicating statistically significantly higher reduction in PPD favoring air-flow compared to SRP alone.[28] The reason for this disparity with the results of the present study is likely due to the fact that the study population also included less well-maintained patients with PPD of at least 4 mm. In another study, higher reductions in PPD were observed for erythritol air-flow when combined with full mouth disinfection compared to full mouth SRP alone.[44]

Regarding furcation involvement, the GBM group exhibited a trend toward improvement ($p = 0.055$) in the number of Class I furcations. Initially, such involvements were registered in four cases, and after the procedures, one of the sites with Class I furcation involvement had resolved. In contrast, in the SRP group, the number of Class I furcations remained at 6, both initially and after the treatments.

Regarding the numbers of gingival recessions of at least 1 mm, no statistically significant differences were found between the groups.

While there were no statistically significant differences between the clinical effectiveness of the procedures during maintenance in the GBM and SRP groups, respectively, it may be anticipated that the procedures themselves offer advantages either to the therapist or the patient. Hence, PROMs have been analyzed as well. Specifically, the issue of pain perceived after the procedures and the overall satisfaction with the protocols were evaluated through a questionnaire. A VAS was used to provide the possibility of assessing the procedures in a semi-quantitative manner. On a basis of a 100 mm VAS the parameter for pain but not that for overall satisfaction showed significant differences for the 2 groups. Interestingly, pain sensation was statistically significantly higher in the GBM group compared to the SRP group (VAS 15 mm vs. 6.6 mm). While these values are quite low for pain, they still existed, indicating that a small proportion of patients perceived both procedures as painful. When interpreting these findings, it is crucial to acknowledge a limitation of the VAS evaluation in the GBM group. It did not distinguish between treatment with ultrasonic devices and air-flow. Therefore, it is not possible to conclusively determine whether the sensation of pain was higher due to air-flow alone, as this effect may have been masked by the concurrent use of ultrasonic

devices. The overall satisfaction was rated with a VAS of 84.8 and 97.3 mm for the GBM and SRP group, respectively. Again, these values did not differ significantly. Here, it needs to be noted that the patient cohort has been familiar to SRP for many years. Moreover, the dental hygienists performing the treatments are all exceptionally highly skilled operators who have been trained for decades using hand instruments.

In recent years, the routine removal of biofilms has been promoted through the use of high-pressure cleaning with suitable powders containing small-sized particles (erythritol 14 μm). Consequently, it's not surprising that dental care providers have expressed skepticism about this innovative method for biofilm removal, questioning both its cost-effectiveness and clinical performance. The initial studies validating air-polishing date back to 2003, with the assessment of the utilized protocol completed in 2020.[45] Nevertheless, the scientific evidence for superiority, equality, or inferiority of this novel concept requires well controlled clinical trials.

The present study was designed to evaluate the clinical effectiveness of a relatively novel protocol termed GBM practiced during SPC in comparison with regular maintenance visits already practiced for years. The major difference between these two protocols were that with GBM the biofilms were revealed by applying disclosing solutions and subsequently removed by the application of air-flow for the subgingival debridement, while the routine procedure did not apply a biofilm disclosing and used hand instrumentation or the application of ultrasonics. Further, the routine procedure included polishing with rubber cups and polishing paste.

The positive patient-perceived outcomes that were occasionally reported in previous studies in favor of air-flowing compared to conventional SRP could not be conclusively confirmed in the present study. The 1-year analysis of the data corroborated the previously expressed notion of a lack of statistical significance in clinical and microbiological parameters following the use of GBM compared to SRP in patients with a good level of oral hygiene undergoing regular SPC.

Scientific rationale: SPC represents a life-long maintenance of periodontally treated patients and includes regular debridement of the treated teeth. The side effects of repeated instrumentations on root surfaces have to be considered during long-term maintenance. A novel modality of rendering SPC called GBM needs to be compared to the conventional debriding of the root surfaces with hand instruments.

Principal finding: Both GBM and SRP yielded similar clinical outcomes with no significant differences in clinical parameters and very little preferences for SRP in patient perceived outcomes.

Practical implication: Both procedures may be recommended for SPC following active periodontal therapy.

AUTHOR CONTRIBUTIONS

Alexandra Stähli: outcome measures and data collection, ethical approval, data analyses and interpretation, drafting of manuscript; Jvana Ferrari: study organization, data collection and data security; Anna Sophia Schatzmann: study organization, data collection and data security, Lucienne Dominique Weigel: outcome measures, data collection; Andrea Roccuzzo: outcome measures, data collection, manuscript writing; Jean-Claude Imber: outcome measures, data collection; Ho-Yan Duong: outcome measures; Sigrun Eick: statistical analyses; Niklaus P. Lang: conceptualization, drafting of manuscript; Giovanni E. Salvi: conceptualization and manuscript writing; Anton Sculean: conceptualization and manuscript writing.

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CONFLICT OF INTERESTS STATEMENT

The authors do not declare any conflict of interest regarding the present study.

ORCID

Alexandra Stähli https://orcid.org/0000-0002-5631-3300
Jean-Claude Imber https://orcid.org/0000-0001-6690-5249

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